JUL - 3 2001

X. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS K 003855

1.0 Date Prepared

December 6th, 2000

2.0 Submitter (Contact)

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3.0 Device Name

A) Proprietary Name: Hyalomatrix™ CO

B) Common Name(s):

1) Synthetic Polymer implant material
2) Surgical implant polymer material
3) Surgical adjunct polymer material

4.0 Device Classification

Ear, nose and throat synthetic polymer material, Class II, CFR 874.3620
Product code: KHJ

5.0 Device Description

F.A.B. Hyalomatrix™ CO is a biomaterial composed of HYAFF®, an ester of hyaluronic acid, a naturally occurring constituent of the extracellular matrix. The device has the appearance of a white, fibrous non-woven pad which acts as a temporary space-occupying material and assists, as an adjunct, the natural healing process by providing a biocompatible scaffolding to aid in the surgical repair.

6.0 Intended Use

Hyalomatrix™ CO is indicated for use as a temporary space-occupying material and as an adjunct for surgical repair in septoplasty, otoplasty, rhinoplasty and in various otorhinolaryngological and head and neck surgical procedures involving cartilage tissue.

7.0 Substantial Equivalence

Hyalomatrix™ CO is a polymeric material for prescription use supplied sterile in individual pouches containing a single 2 cm x 2 cm square of the device.
The subject and predicate devices are intended for use as long term implant materials for ENT surgical repairs. All they use biocompatible materials suitable for surgical use, are sterile, single use.
The difference between the Silicone sheetings and Hyalomatrix™ CO is that the predicate devices are made of silicone, while the subject device is made of HYAFF® 11, a benzyl ester of hyaluronic acid which typically dissolves in 6-8 weeks. This is the same base material of the other predicate product, Epifilm™ Otologic Lamina, which has the same intended use. The difference is that the subject device is in form of a flat non woven pad, whereas all the predicate products are offered in form of thin sheets.

The material comprising Hyalomatrix™ CO has been subjected to extensive biocompatibility testing according to the ISO/EN standards for material testing for toxicity and biocompatibility. The material has been demonstrated non-toxic and biocompatible according to ISO 10993 standards. Additionally, in clinical experience it has presented no new issues of safety when implanted at the level of articular cartilage.

In conclusion, F.A.B. Hyalomatrix™ CO has the same intended use as the predicate devices from which it differs in the physical form, being a flat non-woven pad, and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. Paolo Rampazzo
Quality Assurance Manager, F.A.B.
Fidia Advanced Biopolymers SRL
Via Ponte Della Fabbrica, 3/A
35031 Abano Terme (PD) - Italy

Re: K003855
Trade Name: Hyalomatrix™ CO
Regulation Number: 21 CFR 874.3620
Regulatory Class: Class II
Product Code: 77 KHJ
Dated: May 18, 2001
Received: May 24, 2001

Dear Dr. Rampazzo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Intended Use Statement

510(k) Number (if known): K 003855

Device Name: Hyalomatrix™ CO

Indications for Use: The FAB Hyalomatrix™ CO is an implant material indicated for use as a temporary space-occupying material and as an adjunct for surgical repair in septoplasty, otoplasty, rhinoplasty and various ENT and head and neck surgical procedures involving cartilage tissue.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003855